Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2157719	11/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sterling Urgent Care	507 S Main Street, Hailey, ID	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to verify the accuracy of testosterone at least twice annually since testing began in December 2018. Findings: 1. A record review revealed that the verification of accuracy for testosterone had failed and no documentation of review or corrective action was available at the time of the survey. 2. The laboratory performed approximately 100 testosterone tests in 2019. 3. An interview on November 8, 2019 at approximately 2:00 PM, with the laboratory supervisor, confirmed that the laboratory failed to review unsatisfactory performance for the accuracy of testosterone and that only one sample was submitted for evaluation since December 2018.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to ensure the function checks on the pocHi hematology analyzer were within the manufacturer's established limits prior to running patient specimens

	on each day of patient testing since December 2018. Findings: 1. A review of maintenance logs and instrument printouts revealed that background function checks on the pocHi hematology analyzer where not available at the time of the survey. 2. An interview on November 8, 2019 at approximately 3:30 PM, with the laboratory supervisor confirmed that the laboratory failed to maintain documentation of function checks that were performed prior to running patients samples.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to monitor the accuracy and precision of the complete blood cell count (CBC) controls over a period to detect changes or variances in the test performance since patient testing began in December 2018. Findings: 1. A record review of the quality control documentation for the pocHi hematology analyzer revealed the laboratory failed to monitor the control procedures over time to detect shifts, drifts and trends, which would help to identify errors or problems with the test system. 2. The laboratory ran approximately 1800 tests on the pocHi in 2019. 3. An interview on November 8, 2019 at approximately 4:00 PM confirmed that the laboratory did not print or evaluate cumulative quality control data for the pocHi.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to include for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number on final test reports for analytes performed on the Sysmex pocHi hematology analyzer and the FREND quantitative immunoassay analyzer. Additionally, the address of the

	laboratory was not available on final test reports. Findings: 1. A review of two patient test reports revealed that the laboratory was using birthdates for patient identification and did not have a mechanism in place for positive patient identification. 2. The laboratory performed approximately 300 tests on the FREND and 1800 tests on the pocHi in 2019. 3. An interview on November 8, 2019 at approximately 3:00 PM with the laboratory supervisor and the lead testing personnel, confirmed that the laboratory does not use two unique patient identifies for all tests and that the address of the laboratory does not appear on final reports that are scanned into the electronic medical record.